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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/534,509	03/24/2000	Zenoviy Tkachuk	000152	2421

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EXAMINER
CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
1632	22

DATE MAILED: 05/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/534,509	Zenoviy Tkachuk
Examiner	**Art Unit**
Shin-Lin Chen	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *9-25-02. 11-26-02 and 3-19-03*.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-6 and 8-55* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) *2-5* is/are allowed.

6) ☒ Claim(s) *1, 6, 8-24, 33, and 38-55* is/are rejected.

7) ☒ Claim(s) *25-32 and 34-37* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's amendments filed 9-25-02, 11-26-02 and 3-19-03, and the declaration filed 1-17-03 have been entered. Claim 7 has been canceled. Claims 46-55 have been added. Claims 1, 10, 11, 20-22, 39-45 and 55 have been amended. Claims 1-6 and 8-55 are pending and under consideration.

Claim Objections

1. Claims 6-39 are objected to because of the following informalities: Since claims 6-39 depend on one of claims 1-5, the article "A" in line one of each claim should be changed to "The". Appropriate correction is required.

2. Applicant is advised that should claims 13 and 15 be found allowable, claims 46 and 47 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MEP. § 706.03(k).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 14 recites the limitation "stroke" in line 2. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 16 recites the limitation "allergy" in line 2. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 17 recites the limitation "pain" in line 2. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 18 recites the limitation "fever" in line 2. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 19 recites the limitation "swelling" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Applicant's amendments filed 9-25-02, 11-26-02 and 3-19-03 necessitate these new ground of rejections under 35 U.S.C. 112 second paragraph set forth above.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1, 6, 8-24, 33 and 38-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using yeast RNA to inhibit aggregation of thrombocytes induced by arachidonic acid, to stabilize acid-challenged erythrocyte membrane in

vitro, to inhibit swelling in the model of local inflammation provoked by carrageenan (LPS) in mice, to inhibit NOS activity that is increased during the initial stage of inflammation development in mice, to provide cardioprotective function of yeast RNA in infarction of myocardium in rats, and delay the development of adjuvant arthritis in rat, does not reasonably provide enablement for preventing or treating inflammation or inflammatory-related disorder present in diabetes, atherosclerosis, tumor, hepatitis, any infection, and any neuro-degenerating disease by using yeast RNA at various concentration recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicant's amendments filed 9-25-02, 11-26-02 and 3-19-03 necessitate this new ground of rejection.

Claims 1, 6, 8-24, 33 and 38-55 are directed to a method for the prevention or treatment of inflammation or inflammatory-related disorder present in infarct, arthritis, diabetes, tumor, atherosclerosis, hepatitis, any infection, and any neuro-degenerating disease by administering total yeast RNA, such as yeast RNA isolated from Saccharomyces cerevisiae or Candida utilis, of various concentration as recited in the claims to a mammal via intradermal, hypodermal, intra-abdominal, intramuscular, or intravenous administration, wherein said yeast RNA is in the mammal's blood, and a pharmaceutical composition comprising said yeast RNA.

The specification of the present invention discloses inhibiting aggregation of thrombocytes induced by arachidonic acid, stabilizing acid-challenged erythrocyte membrane in vitro, inhibiting swelling in the model of local inflammation provoked by carrageenan (LPS) in

mice, inhibiting NOS activity that is increased during the initial stage of inflammation development in mice, providing cardioprotective function of yeast RNA in infarction of myocardium in rats, and delaying the development of adjuvant arthritis in rat. The claims encompass preventing and treating inflammation or inflammatory-related disorder present in infarct, arthritis, diabetes, atherosclerosis, tumor, hepatitis, any infection including viral and bacterial infections, and any neuro-degenerating disease by using yeast RNA *in vivo* at various concentration recited in the claims via various administration routes.

The term "pharmaceutical composition" in claims 20-22, 38 and 43-45 implies therapeutic effect *in vivo*. The specification fails to provide adequate guidance and evidence for how to prevent or treat inflammation or inflammatory-related disorder present in diabetes, atherosclerosis, tumor, hepatitis, any infection, and any neuro-degenerating disease by using yeast RNA at various concentration recited in the claims via various administration routes so as to provide therapeutic effects in a mammal. The administration of total yeast RNA to a patient for preventive or curative benefits of a disease has little precedent in the art. The specification fails to provide sufficient description for the types of inflammation or inflammatory-related disorder present in diabetes, atherosclerosis, tumor, hepatitis, any infection including viral and bacterial infections, and any neuro-degenerating disease and how to prevent or treat said inflammation or inflammatory-related disorder by using total yeast RNA *in vivo*. Although the specification provides examples of inhibiting aggregation of thrombocytes induced by arachidonic acid, stabilizing acid-challenged erythrocyte membrane *in vitro*, and inhibiting NOS

activity in mice by using total yeast RNA, those yeast RNA activities can not be extrapolated into successful prevention and treatment of inflammation or inflammatory-related disorder present in diabetes, atherosclerosis, tumor, hepatitis, any infection including viral and bacterial infections, and any neuro-degenerating disease *in vivo*.

Gallin et al., 1992 (Inflammation: Basic Principles and Clinical Correlates, second edition, Raven Press, New York, p. 1-4) states that inflammation involves a complex series of events including dilation of arterioles, capillaries, and venules, exudation of fluids including plasma proteins, and leukocytic migration into the inflammatory focus. There are different types of inflammations that includes allergic (reaginic) inflammation, inflammation mediated by cytotoxic antibodies, inflammation mediated by immune complexes, and inflammation mediated by mononuclear leukocytes. Multiple mechanisms are involved in different types of inflammations. The pathobiologies of different types of inflammation associated with different diseases would vary and it can not be asserted that inhibiting aggregation of thrombocytes induced by arachidonic acid, stabilizing acid-challenged erythrocyte membrane *in vitro*, or inhibiting NOS activity in mice by using yeast total RNA would be predictive of preventive or curative benefit of inflammation or inflammatory-related disorder present in a disease. There is no evidence of record that inhibiting aggregation of thrombocytes induced by arachidonic acid, stabilizing acid-challenged erythrocyte membrane *in vitro*, or inhibiting NOS activity in mice would assert prevention or treatment of inflammation or inflammatory-related disorder present in diabetes, atherosclerosis, tumor, hepatitis, any infection including viral and bacterial infections,

and any neuro-degenerating disease *in vivo*. Thus, one skilled in the art would not know how to use the yeast total RNA to prevent or treat inflammation or inflammatory-related disorder present in diabetes, atherosclerosis, tumor, hepatitis, any infection including viral and bacterial infections, and any neuro-degenerating disease and provide therapeutic effects *in vivo*.

Therefore, it is concluded that based upon the nature of the claimed invention, the state of the art, the unpredictability found in the art, the teaching and working examples provided, and the breadth of the claims that it would require a skilled artisan at the time of the invention undue experimentation to practice over the full scope of the invention claimed.

Conclusion

Claims 1, 6, 8-24, 33 and 38-55 are rejected. Claims 2-5 are in condition for allowance. Claims 25-32 and 34-37 are objected.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MEP. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

S. Chen

Shin-Lin Chen, Ph.D.